



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,460	12/05/2003	Emily J. Reinhard	18438/09029 (01115/1)	9307

7590 04/26/2007
Charles E. Dunlap
P.O. Box 11070
Columbia, SC 29211-1070

EXAMINER

BETTON, TIMOTHY E

ART UNIT	PAPER NUMBER
----------	--------------

1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/728,460		REINHARD ET AL.	
	Examiner		Art Unit	
	Timothy E. Betton		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17 are drawn to a method of inhibiting mitogen activated protein kinase-2 in a subject in need of such inhibition, the method comprising administering to the subject an aminocyanopyridine MK-2 inhibiting compound, or a pharmaceutically acceptable salt thereof, the compound having the disclosed core structure, classified in class 514, subclass 340. If this group is elected, then the below summarized species election is also required.
- II. Claims 18-32 are drawn to a method of preventing or treating a TNF- alpha mediated disease or disorder in a subject in need of such prevention or treatment, the method comprising administering to the subject an effective amount of an aminocyanopyridine MK-2 inhibiting compound, classified in class 514, subclass 340. If this group is elected, then the below summarized species election is also required.

Inventions I, II are related processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product.

See MPEP § 806.05(h). Invention I is distinct from invention II by way of design.

Inhibiting mitogen activated protein kinase-2 is not necessarily a direct indication of a treating a TNF-alpha mediated disease. Invention I is directed toward a method of inhibiting mitogen activated protein kinase-2 in a subject in need of such inhibition, the

Art Unit: 1614

method comprising administering to the subject an aminocyanopyridine MK-2 inhibiting compound. Invention II is directed toward a to a method of inhibiting mitogen activated protein kinase-activated protein kinase-2 in a subject in need of such inhibition with use of a core structure moiety that is associated with an aminocyanopyridine MK-2 inhibiting compound. Invention III is directed toward a method of preventing or treating a TNF-alpha mediated disease or disorder in a subject in need of such prevention or treatment, the method comprising administering to the subject an effective amount of an aminocyanopyridine MK-2 inhibiting compound. In the instant case, the aminocyanopyridine MK-2 inhibiting compound may be used in a materially different process of using the product as in the treatment of same disease states , which mimic TNF-alpha mediated diseases.

Election of Species for Group I

Species Election aminocyanopyridine MK-2 inhibiting compound

Applicant is required to elect one specific moiety for the formula I disclosed in instant claim 1, formula II disclosed in instant claim 8, or formula III disclosed in instant claim10. Applicant is to elect one specific and single core structure species. Applicant is then required to elect one specific moiety of the core structure, i.e., electing a specific group for each disclosed constituent on practicing core structure (formulae I-III) from the plethora of disclosures above in instant claims.

Applicant is required to elect a specific emollient species selected from the group consisting of petroleum-based; sucrose ester fatty acids; polyethylene glycol and derivatives thereof; fatty acid ester type; alkyl ethoxylate type; fatty acids, particularly

Art Unit: 1614

those having from about 8 to about 28 carbon atoms in their fatty chain; fatty acid ester ethoxylates; fatty alcohol type; polysiloxane type; propylene glycol and derivatives thereof; glycerine and derivatives thereof, including glyceride, acetoglycerides, and ethoxylated glycerides of C8-C28 fatty acids; spermaceti and other waxes; fatty alcohol ethers, particularly those having from about 8 to about 28 carbon atoms in their fatty chain, propoxylated fatty alcohols; other fatty esters of polyhydroxy alcohols; lanolin and its derivatives; kaolin and its derivatives; sorbitol and its derivative; trihydroxy stearin; ester derivatives and mixtures thereof.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant is required to define. Currently, claims 1 are generic to the above electable species

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

Art Unit: 1614

of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Should the applicant traverse on grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is so. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species for Group II

Species Election for Species Election aminocyanopyridine MK-2 inhibiting compound and TNF-alpha mediated disease

Applicant is required to elect one specific moiety for the formula IV disclosed in instant claim 18. Applicant is to elect one specific and single core structure species. Applicant is then required to elect one specific moiety for the instant core structure, i.e., electing a specific group for each disclosed constituent on practicing core structure (formulae IV) from the plethora of disclosures above in instant claims.

Applicant is required to elect a specific TNF-alpha mediated disease or disorder from the extensive disclosure of instant claim 23.

Election/Restrictions Proper

MPEP §809.02(d) states “[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary.” In this instant case, the claims cited are of such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined together.

The present claims are directed toward a Present claim 1 and claims dependent from claim 1 for example disclose a multiplicity of active drugs and derivatives thereof. It would, therefore, present a serious search burden to the Examiner if all claimed species were searched together due to the multiplicity of varying susceptibilities, properties and distinct properties, if all of the species were examined together.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

Ardin H. Marschel 4/22/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER